

Remarks

Claims 1, 4-6, 8-15 and 103-105 are pending in the application. The Examiner has rejected Claims 1 and 3-15. Claims 3 and 7 are cancelled. Claims 1, 4, 8-11 have been amended. New Claims 103-105 have been added. Support for the new Claims are found in paragraphs 108-110 and figures 13A-F of the Applicant's publication. No New matter has been introduced. Reconsideration and allowance are respectfully solicited.

Examiner Interview

Applicant thanks Examiner Melanie Jo Hand for the time that she spent on January 8, 2008, discussing Applicant's proposed amended claim 1 over the telephone with Applicant's attorney of record, Marc E. Brown, in-house counsel Shervin Nakhjavan, Arman Nadershahi, and the inventor Ramez Shehada.

The Examiner advised that the proposed amendments to claim 1 overcome the Jenkins patent. The Examiner also advised that she would need to do a supplemental search and to verify that Applicant did not previously restrict its claims to a single lumen.

Applicant now provides further comments in support of the claims.

Claim Rejections Under 35 U.S.C 102

The Examiner has rejected Claims 1 and 3-6 and 9-11 under 35 U.S.C. 102(e) as being anticipated by Jenkins et al. (US 6,645,199). Claim 3 is now cancelled the content of which is incorporated into claim 1.

Claim 1 as now amended recites an implantable surgical drain to be placed against at least one tissue within a patient's body for draining fluid and sensing at least one physiological property of the tissue comprising: an elongated conduit housing

configured to be implanted in the patient's body and to rest against a substantial length of a first tissue within of the body, and to drain wound fluid from the body, the elongated conduit comprising: a first and a second surface on an outer side and along the length of the elongated conduit; a plurality of drain openings in the first and the second surface positioned along substantially the entire length of the elongated conduit, configured to drain wound fluid from the body; a first and a second drain lumen positioned within the elongated conduit housing in fluid communication with the plurality of the drain openings; at least one sensing element positioned along the first surface in proximity to the drain openings of the elongated conduit configured to sense a physiological property of the first tissue; and at least one inflatable compartment positioned within the elongated conduit housing, between the first and the second drain lumens, positioned behind the at least one sensing element, configured when inflated to push the at least one sensing element in substantially orthogonal direction with respect to the first surface against the first tissue so as to enhance contact between the sensing element and the first tissue; and a tube in fluid communication with the first and the second drain lumens configured to transport the drained wound fluid out of the body.

On page 3, lines 2-4, of the OA, the Examiner stated that "*A recitation of the intended use (i.e. draining of wound fluid) of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art*".

Applicant has amended the Claim 1 to clearly set forth the Applicant's claimed invention. Claim 1 as now amended establishes the functional and the structural

difference between the claimed invention and the prior art as suggested by the Examiner.

The prior art to Jenkins et al. (US 6,645,199) does not teach the draining of wound fluid, the drain openings along substantially the entire length of the invasive portion of the apparatus, or the tube in fluid communication with the invasive portion of the apparatus to transport the drained wound fluids out of the body. In fact, Jenkins does not have the capability of or even the need for removing any body fluid from the body as explained below.

On page 2 of the office action, the Examiner claims that "*Col. 5, lines 27-30 in which Jenkins teaches that the device has application in the diagnosis and treatment of ailments of the gall bladder, prostate and brain, all of which necessitate drainage of bodily fluid for treatment to occur.*" The Applicant respectfully disagrees. The conclusion drawn by the Examiner that the Jenkins' device must be draining bodily fluid prior to treatment is incorrect. The Jenkins's apparatus (10) performs its therapeutic function by using the coagulation electrodes to heat the tissue and create tissue coagulation lesions and then uses the diagnostic electrodes (104) to detect electrical activity and determine whether a curative lesion has been formed. Therefore, the therapeutic and diagnostic functions of the apparatus (10) of Jenkins do not require the drainage of a bodily fluid as claimed by the examiner. If the Jenkins apparatus (10) was draining body fluid, it would be draining valuable blood from the pulmonary vein where the apparatus is placed, which would endanger the patient's life. Furthermore, there is no mention of any draining or sampling of a body fluid throughout Jenkins' disclosure.

Additionally, Claim 1 now requires an elongated conduit housing, wherein the

housing includes two drain lumens within it, a plurality of openings in communication with the drain lumens and wherein the inflatable compartment is positioned within the housing in between the two drain lumens. The inflatable compartment is also positioned behind the sensing element and configured to push the sensing element in an orthogonal direction with respect to the first surface of the conduit housing, wherein the surface includes the plurality of the drain openings and the sensing element.

In figure 10A of Jenkins, there are no drain lumens within the catheter 114 nor is the inflatable device 118 between any drain lumens. None of the embodiments disclosed in Jenkins' patent teach or suggest the arrangement of Applicant's surgical drain. Indeed, Applicant's present surgical drain device having a plurality of lumens and a comparatively smaller inflatable compartment would not even work for Jenkins' therapeutic purposes.

Furthermore, during use, the probe (12) of Jenkins is manually oriented relative to the separate probe (16) so as to position its loop structure (14) with its coagulation electrodes (22) and temperature sensors (196) on the distal side of the inflatable push structure (118) (See Figures 2 and 12A). Applicant agrees the expansion of the inflatable push structure (118) will push the loop structure (14) of figure 1 against the tissue (column 6, lines 25-26 and lines 29-32, column 13, lines 58-61). However, the inflatable push structure (118) shown in Figure 10A does not push the mapping basket 100 with its diagnostic electrodes (104) (not a sensing elements) against the tissue as claimed by the Examiner.

Unlike the claimed invention, the apparatus disclosed by Jenkins et al. (a) does not drain body fluids, (b) does not have the structural features to

drain body fluids or wound fluid, (c) does not have the inflatable compartment structure positioned within the conduit housing between the plurality of drain lumens, and behind the sensor, and (d) does not push the sensor in an orthogonal direction with respect to the first surface, wherein the first surface includes the sensor and the plurality of drain openings for draining wound fluids.

Therefore, Jenkins et al. fail to anticipate the features and elements of claim 1.

Claims 4-6, 8-15 and 103-105 depend from a non-anticipated claim and are thus themselves also not anticipated.

Claim Rejections under 35 U.S.C 103

The Examiner has rejected Claims 7 and 8 under 35 U.S.C 103(a) over Jenkins et al. in view of Fiddian-Green (US 6,334,064). Claim 7 is now cancelled and its content has been incorporated into Claim 1. The Applicant respectfully requests reconsideration and allowance of claim 1 in view of the current amendment.

Fiddian-Green does not remedy the deficiencies of Jenkins et al.'s. Specifically, Fiddian-Green, as in Jenkins et al., (a) does not have an elongated conduit housing having a first surface, wherein the first surface includes a plurality of drain openings along with a sensing element in proximity to the drain openings, and to rest against the tissue and drain wound fluids while sensing element senses the physiological properties of the tissue; (b) does not have an inflatable compartment structure positioned within the elongated conduit housing between a plurality of drain lumens, and behind the sensor, and (c) does not push the sensor in an orthogonal direction with respect to the first surface of the elongated conduit.

The Examiner further asserts that Witten et al. (US 3,680,562), Torre

et al. (US Patent Publication 2002/0055757), and Schoolman variously teach the additional limitations of dependent claims 12-15. However, none of these references remedy the deficiencies of Jenkins et al. as discussed above with respect to claim 1.

Therefore, claims 8, 12-15 are not obvious and their allowance is also respectfully solicited.

New Claims

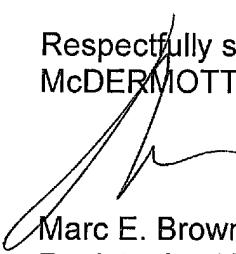
New dependent claims 103-105 have been added. No new matter has been introduced. Support for the new claims is found in paragraphs 108-110 and figures 13A-F of the Applicant's publication.

CONCLUSION

Applicant respectfully submits that the above amendment and remarks place this application in a condition for allowance, which the Applicant respectfully solicits.

Please charge any shortage in fees due in connection with the filing of this paper to Deposit Account 501946 and please credit any excess fees to such deposit account and reference attorney docket no. 64693-0103.

Respectfully submitted,
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